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FIRST RESULTS OF THE COVID-19 PATIENTS TREATED WITH THE SERAPH® 100 MICROBIND® AFFINITY FILTER (COSA) REGISTRY

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BACKGROUND AND AIMS: The COVID-19 pandemic has serious impact on health and economics worldwide. Despite the recent advent of SARS-Cov-2 vaccines, treatment options are needed, yet pharmacologic interventions remain limited. Several extracorporeal treatments are currently explored concerning their potential to improve the clinical course and outcome of critically ill patients with COVID-19. The Seraph® 100 Microbind® Affinity adsorber (Exthera Medical, CA, USA) has recently been introduced for the elimination of several pathogens from the blood and an emergency authorization in patients with COVID-19 was granted by the FDA. Bacteria, viruses (including the SARS-CoV-2 spike glycoprotein), fungi and toxins have been shown to bind to the immobilized heparin on the ultra-high molecular weight polyethylene beads of the device in a similar way to the interaction with heparan sulfate on the cell-surface and are thereby removed from the bloodstream. Here we report the interim analysis of the COVID-19 patients treated with the Seraph® 100 Microbind® Affinity filter (COSA) registry. The goal of the registry is to gather data regarding the safety and efficacy of the Seraph® 100 in the treatment of COVID-19 patients.

METHOD: Participating sites were advised to insert patient data of COVID-19 patients, treated with the Seraph® 100, during their hospital stay into the COSA registry (ClinicalTrials.gov Identifier: NCT04361500). A total of 66 items were asked in a web-based platform.

RESULTS: Until January 2021, 33 patients with 39 treatment sessions form six different hospitals were reported to the register (seven female, median age 61 years, Table 1). The patients were treated between March and December 2020. Eleven patients with a hospital admission between March and August and 22 between September and December 2020. The Seraph® 100 treatment was initiated 9 days after symptom onset, without any difference between survivors and non-survivors. Overall, a mortality of 27% was reported. Serious comorbidities (as preadmission immunosuppressive therapy, lung fibrosis or CKD5T) were reported in all of the non-survivors. Invasive ventilation was needed in 67% of these patients when Seraph treatment was initiated. A non-significant trend towards higher Ferritin levels in non-survivors (2000 (1963 – 8326) vs. 989 (644 – 2000), p=0.09) was reported. All treatments were well tolerated, three clotting events were reported.

CONCLUSION: Viral SARS-CoV-2 RNA is frequently (up to 78%) seen in the blood of critically ill COVID-19 patients and correlates with the severity of the disease. The Seraph® 100 can bind to viral spike protein, proinflammatory cytokines may be reduced by the device and hemodynamic stabilization has been reported during the Seraph®100 treatment of COVID-19 patients. Platelets can be hyperactivated in association with SARS-CoV-2 proteins and thus presumably trigger the hypercoagulation and thrombosis. In this context, the removal of SARS-CoV-2 proteins to prevent hyperactivated platelets appears to be a sensible approach. All reported deaths were associated with serious preexisting comorbidities, immunosuppression, dialysis dependent renal failure, or a combination of these factors. Hence, Seraph® 100 treatment may be most beneficial in COVID-19 courses of patients without multi organ failure. More clinical data is needed to describe possible benefits of the Seraph®100 in the treatment of COVID-19 patients.

		Survivor N = 24 (73%)	Non-Survivor N = 9 (27%)	Total N = 33
DEMOGRAPHICS				
Median age	years	57 (51 - 68)	67 (54 – 70)	61 (54 – 68)
Female sex	No	4 (17%)	3 (33%)	7 (21%)
Caucasian race	No	18 (75%)	7 (78%)	25 (76%)
Height	cm	175 (174 – 179)	172 (170 – 180)	175 (172 – 179)
Weight	kg	91 (80 – 119.3)	88.5 (85.5 – 96)	90 (80 - 107)
Symptom onset - Seraph	days	9 (6 – 12)	10 (5 – 17)	9 (6 – 13)
Ferritin	ng/mL	989 (644 - 2000)	2000 (1963 – 8326)	1203 (830 – 2000)
Leucocyte count	1000/µL	10 (4.6 – 16)	12.7 (10.4 – 13.9)	11.3 (5.5 – 14.2)
d-dimer	mg/L	1.78 (1 – 3.3)	3.5 (1 – 11.7)	2.1 (1 – 3.9)
Dialysis dependency	No	7 (29%)	4 (44%)	11 (33%)
Bacterial superinfection	No	6 (25%)	6 (66%)	12 (36%)
SERAPH TREATMENT				
Blood flow	ml/min	200 (150 – 250)	225 (195 – 250)	200 (172 – 250)
Duration	hours	4 (4 – 5)	4.2 (3.9 – 10.5)	4.1 (4 – 5)
Citrate anticoagulation	No	3 (13%)	4 (44%)	7 (21%)
Stand-alone treatment	No	15 (63%)	1 (11%)	2 (6%)
Clotting events	No	3 (13%)	0 (0%)	3 (9%)